

Outcomes of surgical coronary revascularization performed pre-solid abdominal organ transplant

Running Head: Role of CABG Pre-Abdominal Transplant

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ABSTRACT

Background: Cardiac risk stratification and coronary angiography are routinely performed as part of kidney and liver transplant candidacy evaluation. There are limited data on the outcomes of surgical coronary revascularization in this patient population. We investigated outcomes in patients with end stage renal or hepatic disease undergoing coronary artery bypass grafting (CABG) to attain kidney or liver transplant candidacy.

Methods: Retrospective analysis of all patients who underwent isolated CABG at our institution between 2010 and 2016. Patients were divided into two cohorts: Pre-transplant (those undergoing surgery to attain renal or hepatic transplant candidacy) and Non-transplant (all others). Baseline characteristics and postoperative outcomes were compared between groups.

Results: A total of 1801 patients were included: 28 in Pre-transplant (n=22 kidney, n=7 liver) and 1773 in Non-transplant. Major adverse postoperative outcomes were significantly greater in Pre-transplant compared to Non-transplant: 30-day mortality (14.3% vs. 2.8%, $p=0.009$), neurologic events (17.9% vs. 4.8%, $p=0.011$), re-intubation (21.4% vs. 5.8%, $p=0.005$) and total postoperative ventilation (5.2 vs. 5.0 hours, $p=0.0124$). One- and five-year mortality in Pre-transplant was 17.9% and 53.6%, respectively. Of the Pre-transplant cohort, three patients (10.7%) underwent organ transplantation (all kidneys) at a mean 436 days after CABG. No patients received liver transplantation.

Conclusions: Outcomes following CABG in the pre-kidney and pre-liver transplant population are poor. Despite surgical revascularization, the vast majority of patients do not ultimately undergo transplantation. Revascularization strategies and optimal management in this high-risk population warrants further study.

Coronary artery disease (CAD) is highly prevalent among patients with end-stage kidney or liver disease. Studies indicate that over 70% of patients on hemodialysis (HD) have some form of cardiovascular disease (CVD), with 40% to 81% having CAD.¹⁻⁸ Up to 26% of patients awaiting orthotopic liver transplantation (OLT) have CAD.^{2,3} Moreover, the leading cause of death pre- and post-transplantation is CVD, especially within the early post-transplantation period.^{2,4-6}

Despite the survival benefit of solid abdominal organ transplantation, matched donors remain scarce.⁸ Consequently, cardiac risk stratification is an integral part of the candidacy evaluation of potential organ recipients. However, there remains controversy in (1) the proper guidelines to follow,⁹⁻¹³ (2) the utility of noninvasive tests like dobutamine-stress echocardiography (DSE) and myocardial perfusion studies (MPS) to screen for clinically significant CAD,¹⁴⁻¹⁶ (3) angiographically significant coronary lesions,^{5,17,18} and (4) the efficacy of coronary revascularization in improving outcomes and transplant candidacy.¹⁹⁻²³ Despite such ambiguity, patients found to have CAD are routinely referred for coronary revascularization before being cleared for transplant eligibility.

Isolated coronary artery bypass grafting (CABG) outcomes are among the most heavily studied, with recent Society of Thoracic Surgeons (STS) data indicating overall mortality approaching less than 2%.²⁴ Yet, there are few published results describing outcomes in patients who undergo CABG in order to attain abdominal organ transplant candidacy. Moreover, the likelihood of a patient ultimately receiving the desired organ transplant after CABG is unknown. Our institution is a high-volume renal and hepatic transplantation center, and we sought to investigate CABG outcomes in this population. To our knowledge, this study is the first to

examine the incidence of the desired organ transplantation after undergoing CABG to achieve candidacy.

MATERIAL AND METHODS

The Institutional Review Board of Indiana University approved this retrospective study. An institutional STS database was queried to identify all patients who underwent isolated CABG at our institution between 2010 and 2016. Data were extracted from this registry and from individual medical records. Patients who underwent CABG in order to achieve abdominal organ transplant candidacy were identified by a separate query of each individual medical record for the term “*transplant*” followed by a manual confirmatory review of each chart. The study cohort was then divided into two groups: “Pre-transplant” (those undergoing surgery to achieve liver or kidney transplant candidacy) and “Non-transplant” (all others).

In addition, a state-wide medical registry (Regenstrief Institute, Indianapolis, IN) was utilized to assess post-CABG outcomes of the Pre-transplant group such as transplant status and survival. This allowed data capture even if a patient sought medical attention outside our institution, as long as the care was obtained within Indiana. Primary outcomes studied were 30-day mortality and incidence of desired solid abdominal organ transplantation after CABG. Secondary outcomes included postoperative variables including length of stay (LOS), mechanical ventilation time, blood product usage, stroke, pneumonia, readmission, reintubation, and time to transplantation. Pre-transplant and Non-transplant groups were compared. A secondary subset analysis was then conducted comparing Pre-transplant end stage renal disease (ESRD) patients and Non-transplant patients with ESRD.

Statistical Methods

Descriptive analysis was performed to examine the distribution of patient characteristics and postoperative outcomes in the sample groups using frequency distribution for categorical variables and median (Interquartile Range) for continuous variables. Bivariate analyses were completed to investigate the outcomes of Pre-transplant compared to Non-transplant using Fisher's exact test and Wilcoxon rank-sum test for categorical and continuous variables, respectively. Thirty-day survival analysis was performed using log-rank test to determine the difference between Pre-transplant and Non-transplant and was displayed using Kaplan-Meier plots. The Hazard ratio (HR) [95% CI] was also reported using bivariate Cox proportional hazard methods to estimate the relative risk of mortality among Pre-transplant patients compared to Non-transplant after verifying the proportionality of hazards assumption. Significant difference between groups was assessed using a type I error rate of 0.05. All analyses were performed using Stata SE/14.2 (StataCorp, L.P., College Station, TX).

RESULTS

A total of 1801 patients were included in the study. Baseline demographic and preoperative characteristics are listed in Table 1 for Pre-transplant (n=28) and Non-transplant (n=1773). Pre-transplant consisted of 22 patients with ESRD and 6 patients with end-stage liver disease (ESLD). Of these, one patient had combined ESRD-ESLD. Non-transplant was comprised of all other CABG patients. All Pre-transplant ESRD patients were dialysis-dependent, while the median Model for End-Stage Liver Disease (MELD) score in Pre-transplant ESLD was 10.49 (IQR 8.72) (Table 2).

For the entire cohort, median age was 63 years (IQR 14.0) and 72.8% were male. Diabetes, renal failure/dialysis, and liver disease were significantly more common in Pre-

transplant. Unstable angina or acute coronary syndrome were significantly more common in Non-transplant, while the majority of Pre-transplant patients were asymptomatic or had stable angina (Table 1). 71.4% of Pre-transplant cases were classified as Elective, 28.6% were Urgent, and none were Emergent. In Non-transplant, 49.1% were Elective, 46.6% Urgent, and 4.3% Emergent.

Postoperative 30-day mortality was significantly different between Pre-transplant and Non-transplant (14.3% and 2.8%, respectively, $p=0.009$) (Table 3 and Figure 1). For Pre-transplant, the predicted 30-day mortality based on the STS risk calculator was 5.1%. The incidence of receiving the desired abdominal organ transplant during the entire follow-up period was low: of all Pre-transplant patients, three (10.7%) underwent renal transplant (all were deceased donor kidneys) and none underwent liver transplant. The three renal transplants occurred at 337, 426, and 544 days following CABG. Of the seven Pre-transplant ESRD patients, one had post-CABG complications (sepsis, new onset dialysis-dependent renal failure, gastrostomy tube-dependent) which precluded transplant eligibility, two recovered liver function after successful medical treatment of hepatitis C (HCV), one was lost to follow-up, and three died during the follow-up period.

Other postoperative outcomes were also notably different between Pre-transplant and Non-transplant, with Pre-transplant having significantly worse outcomes for essentially all secondary outcome measures except for sepsis and 30-day readmission (Table 3).

A subset analysis was performed to compare between Pre-transplant ESRD patients (all dialysis-dependent) with Non-transplant ESRD dialysis-dependent patients. Baseline characteristics were not different between these two groups (Table 4). Of Pre-transplant ESRD, 52.4% were on hemodialysis and 47.6% on peritoneal dialysis, with the mean duration on

dialysis of 34.7 months. This data was not available for the Non-transplant ESRD group. Acute coronary syndrome or unstable angina were more common in Non-transplant ESRD, while 45.5% of Pre-transplant ESRD were asymptomatic. Postoperative outcomes including 30-day mortality and postoperative adverse events were similar between the two (Table 4).

COMMENT

Current literature on coronary revascularization to attain abdominal organ transplant candidacy yields conflicting results regarding outcomes and survival.^{20-23,25,26} Retrospective reviews by Felix et al. and Patel and colleagues reported no survival advantage of revascularization by percutaneous coronary intervention (PCI) or CABG prior to abdominal organ transplantation over coronary angiography without intervention.^{27,28} On the other hand, Maddur et al. showed that PCI revascularization led to improved outcomes after OLT, while Kumar and associates found that coronary revascularization while awaiting organ transplant improved 1- and 3-year survival.^{25,28}

Our results from the present study indicate that CABG in patients undergoing candidacy evaluation for renal or hepatic transplantation have poor outcomes. Our institutional protocol is to thoroughly review these patients in a combined cardiology-cardiac surgery “Heart Team” conference before proceeding with surgical revascularization. Nonetheless, these patients had short-term mortality of 14.3%, which far exceeded that predicted by the STS risk calculator, and had 5 times greater mortality than all other isolated CABG patients combined. Both Pre-transplant ESRD and ESLD patients had similar 30-day mortality, underscoring the inherent high-risk of all such patients with end-stage organ disease. Intermediate- and long- term outcomes were similarly poor, with 1- and 5- year all-cause mortality of 17.9% and 53.6%,

respectively. It is feasible that the intermediate- and long- term deaths are due to either underlying kidney or liver disease, or due to intrinsic cardiac disease. The exact cause of death beyond 30-days was not available and could not be verified for this study.

We further analyzed Pre-transplant ESRD patients by comparing this group to Non-transplant dialysis-dependent ESRD patients. As expected, these two groups were similar in all characteristics except for presenting status, with more asymptomatic patients in Pre-transplant and more acute coronary syndrome patients in Non-transplant. 30-day mortality was greater in the Pre-transplant group (9% vs. 5%, $p=0.711$) although this was not statistically significant. All other postoperative outcomes were also similar. This subgroup analysis suggests that perhaps the poor outcomes in Pre-transplant ESRD may be a consequence of the underlying renal disease itself rather than being attributable to renal transplant candidacy per se.

Results of the study's other primary outcome--the incidence of desired organ transplantation after CABG--are also remarkable, and, quite frankly, unexpected. Pre-transplant patients underwent CABG in order to attain transplant eligibility, but the majority died within 5 years of surgery *without* receiving the desired organ. Our institution is a major abdominal organ transplant center, with leading volumes of kidney and, in particular, liver, transplantation. Yet, we found that only three (10%) of the Pre-transplant patients ultimately received the desired organ after CABG: all were deceased donor kidney transplants, which occurred at 11 months, 14 months, and 18 months after CABG. These wait times were relatively short, given that the median wait time for a kidney transplant is 45.4 months at our institution and 50.3 months nationally.⁷ The reason for this low transplant rate is unclear; unfortunately, it was not possible to ascertain retrospectively whether/when patients were "listed" and whether donor kidneys were offered and not accepted. These data points could aid future decision making on whether to offer

CABG. We surmise that the value of performing high-risk CABG could be justified if a patient is likely to become actively placed on the waiting list, but perhaps less so if predicted transplant eligibility likelihood is low. While this could be mitigated by performing CABG only after a patient is “listed,” at present most centers (including ours) do not place patients on a waiting list until known CAD is treated.

None of the Pre-transplant ESLD patients underwent transplantation over the 5-year follow-up period. This is particularly surprising given our institution’s relatively short wait time for OLT (median 2.1 months vs. 10.7 months nationally).⁷ Of the Pre-transplant ESLD patients, three had documented reasons that precluded transplant eligibility. The remainder survived CABG beyond 30-days but did not undergo OLT for unknown reasons. These patients did not have any notable incidence of pulmonary hypertension or heart failure, which in some cases may benefit from combined heart-liver transplant (not offered at our institution) albeit with more difficult donor-recipient matching due to the need for two simultaneous organs.

For both ESRD and ESLD, one explanation for the low transplantation rate could be that the patients underwent CABG at a very early stage of the candidacy evaluation process before even rough estimates of eligibility could be assessed. If the cardiac evaluation were performed after other components of the candidacy screening process, patients with low likelihood of attaining candidacy would already be excluded and thus not referred for coronary revascularization. With this approach, the two ESLD patients in our study who recovered after medical management of HCV, for example, would likely have been referred for revascularization *after* being deemed not transplant candidates due to hepatic recovery. Without overt ESLD, these patients could then have undergone much lower-risk CABG instead. We could not accurately identify, for purposes of this study, where in the transplant candidacy evaluation

process each patient was at the time of referral for CAD. Obtaining this information may be beneficial for future prospective studies.

Interestingly, the MELD score for the Pre-transplant ESRD group was higher (19.7) than that for ESLD (10.5). This is explained by the fact that the ESRD patients were dialysis-dependent and had elevated creatinine values, both of which result in a high MELD score even in the absence of defined liver disease. On the other hand, the ESLD group MELD was relatively low (although 25% of all patients eligible for OLT at our institution have MELD score between 6 and 14) because our general practice, with Heart Team discussion, is to refrain from offering CABG in patients with MELD > 15 in the setting of intrinsic hepatic disease. In other words, ESLD patients with MELD > 15 referred for CAD evaluation would have been declined for CABG and offered PCI instead, and thus would not be included in the present study. We do, however, regularly perform CABG in patients with MELD > 15 if we suspect the elevated score is primarily due to renal dysfunction (hence the higher MELD score in the Pre-transplant ESRD group). A future study examining the treatment decision and outcomes of ESLD patients with MELD > 15 who were referred for revascularization as part of a transplant candidacy evaluation would shed light on this particular population.

Pre-transplant patients also had significantly higher post-CABG morbidity than Non-transplant in nearly all secondary outcomes studied. Postoperative complications were more frequent in Pre-transplant than Non-transplant by almost all metrics, again highlighting the high-risk associated with these underlying co-morbidities.

Given the high prevalence of cardiovascular disease and CAD in ESRD and ESLD patients, pre-transplant cardiac assessment is justified. Yet, the need for routine coronary angiography and revascularization for the sake of achieving transplant candidacy remains

unclear.^{1,5,9,13} Some of this ambiguity may be due to poor reliability of non-invasive testing such as DSE and MPS in this particular patient population.^{15,17,29} While the American Heart Association and American College of Cardiology do not recommend non-invasive testing for non-cardiac surgery in asymptomatic patients with good functional capacity even in the presence of certain risk factors, because of the high incidence of significant CAD in pre-transplant patients, many centers, including ours, have traditionally performed angiography in these patients.^{5,9,10} However, the definition of clinically significant disease in this group may differ from the general population.^{5,30} Perhaps intervention in the pre-transplant population should be reserved for patients with certain clinical and angiographic characteristics (critical left main disease, for instance), especially in asymptomatic patients.¹⁸ A more targeted approach deserves further study.

Some have posed convincing arguments in favor of abandoning screening altogether for asymptomatic kidney transplant candidates since receiving a kidney transplant in and of itself lowers long-term cardiovascular-related mortality.¹³ Because ESRD and ESLD patients are inherently higher risk for CABG, one proposal could be that only those with a greater likelihood of ultimately receiving the desired transplant should undergo surgery. In other words, as our study shows, if the chances of receiving the desired transplant are exceedingly low at our center, then should we be subjecting these patients to high-risk CABG? One proposal could be that these patients must be discussed in conjunction with the Heart Team and the transplant evaluation team together so that a holistic picture of eligibility likelihood and stage of candidacy assessment can be considered.

Perhaps the most significant limitation of this study is inherent to its design as a single-center, retrospective study with low sample size. We tried to mitigate this by utilizing multiple

databases, including a statewide registry that captures patient data from care obtained outside our institution. It is certainly possible that some Pre-transplant patients chose to transfer care to another state, which we would not be able to capture in this study. The low sample size was simply a function of the relatively rare nature of this particular patient population. The inclusion dates were maximized to capture all available patients within the existing data registries.

An international randomized controlled trial addressing this topic of CAD in pre-transplant patients is already underway (Canadian-Australasian randomized trial of screening kidney transplants, or CARSK) in which transplant candidates on the wait list are randomized to no CAD screening versus current screening and intervention protocols.^{13,31} We anticipate this study to shed valuable data on the utility of preemptive coronary revascularization. Future studies could further delineate the appropriate role of CABG in this patient population with possible mechanisms to reduce perioperative risk and account for cost and economic impact.

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Table 1. Patient characteristics by study group

Characteristic	Non-Transplant (n=1,773)	Pre-Transplant (n=28)	p-value
Age, years	63(14)	63(5)	0.4520
Gender			>0.999
Male	1,290(72.76)	21(75.00)	
Female	483(27.24)	7(25.00)	
Body Mass Index			0.219
Underweight	18(1.02)	1(3.57)	
Normal	289(16.30)	7 (25.00)	
Overweight	613(34.57)	8(28.57)	
Obese	853(48.11)	12(42.86)	
Chronic Lung Disease			0.475
Mild	284(16.02)	8(28.57)	
Moderate	126(7.11)	1(3.57)	
Severe	70 (3.95)	1 (3.95)	
Unknown	25(1.41)	0	
Diabetes	918(51.78)	23 (82.14)	0.002
Hypertension	1,606(90.58)	27 (96.43)	0.509
Immunocompromised	92(5.19)	4 (14.29)	0.058
Dialysis-dependent	61(3.44)	22(78.57)	<0.0001
Cerebrovascular Disease	284(16.02)	9(32.14)	0.050
Liver Disease	63(4.65)	8(33.33)	<0.0001
Tobacco Use			0.118
Never	712(40.16)	14(50.00)	
Current	380(21.43)	3(10.71)	
Former	240(13.54)	7(25.00)	
Last Creatinine, mg/dL	1(0.38)	4.73(3.98)	<0.0001
MELD Score	8.15(2.89)	18.33(11.27)	0.0013
Presentation			<0.0001
Non-STEMI	379(22.39)	4(14.29)	

STEMI	99(5.58)	0	
Unstable Angina	603(34.01)	2(7.14)	
Stable Angina	357(20.14)	6(21.43)	
Asymptomatic	317(17.88)	16(57.14)	
Status			0.073
Elective	870(49.07)	20(71.43)	
Urgent	827(46.64)	8(28.57)	
Emergent	76(4.29)	0	

Categorical data presented as number(%) unless otherwise indicated. Continuous data presented as Median(Interquartile Range). MELD, model for end-stage liver disease; STEMI, ST-elevation myocardial infarction

Table 2. Postoperative outcomes by study group

Postoperative Outcome	Non-Transplant (n=1,773)	Pre-Transplant (n=28)	p-value
30-Day Mortality	50(2.82)	4 (14.29)	0.009
Length of Stay, days	6(3)	8(6.5)	0.0008
Total Ventilation, hours	4(5)	5.19(17.44)	0.0124
Surgical Site Infection	17(0.96)	2(7.14)	0.058
In-Hospital Postoperative Events	650(36.66)	16(57.14)	0.026
Neurologic	85(4.79)	5(17.86)	0.011
Pneumonia	76(4.29)	5(17.86)	0.035
Sepsis	21(1.18)	0	>0.999
Cardiac Arrest	43(2.43)	4(14.29)	0.021
Blood Product Transfusion	618(34.86)	18 (64.29)	0.001
Re-intubation	103(5.81)	6 (21.43)	0.005
30-day Readmission	44(2.48)	2(7.14)	0.164

Categorical data presented as number(%) unless otherwise indicated. Continuous data presented as Median(Interquartile Range).

Table 3. Patient characteristics and postoperative outcomes by Pre-transplant organ failure group

Characteristic/Outcome	Pre-Transplant ESRD (n=22)	Pre-Transplant ESLD (n=7*)
Age, years	63.5(6)	63(4)
Gender		
Male	17(77.27)	5(71.43)
Female	5(22.73)	2(28.57)
Diabetes	19(86.36)	5(71.43)
Hypertension	21(95.45)	7(100)
Dialysis-dependent	22(100.0)	1(14.29)
Ejection Fraction, %	47.7(13.99)	49.7(9.44)
Cerebrovascular Disease	8(36.36)	1(14.29)
Immunocompromised	3(13.64)	1(14.29)
Liver Disease	2(11.11)	7(100)
Viral Hepatitis (HCV)	1(50.0)	4(57.14)
Non-alcoholic steatohepatitis	1(50.0)	2(28.57)
Autoimmune hepatitis	0	1(14.29)
MELD Score	19.71(0)	10.49(8.72)
Pulmonary Hypertension (\geq moderate)	2(9.09)	0
Noninvasive Stress Test		
Positive	8(36.36)	2(28.57)
Normal	5(22.73)	2(28.57)
Unknown	9(40.91)	3(42.86)
Presentation		
UA/Non-STEMI	4(18.18)	2(28.57)
STEMI	0	0
Stable Angina	3(13.64)	3(42.86)
Asymptomatic	15(68.18)	2(28.57)
CAD Anatomy		
Left Main	11(50.00)	5(71.43)

2-vessel	1(4.5)	0
3-vessel	10(45.45)	2(28.57)
Postoperative Outcomes		
30-Day Mortality	3(13.6)	1(14.29)
Length of Stay, days	8(5)	9(19)
Total Ventilation, hours	5(18.3)	8.18(16.95)
Surgical Site Infection	1(7.14)	1(20.0)
In-Hospital Postoperative Events	12(54.55)	5(71.43)
Neurologic	4(18.18)	1(14.29)
Pneumonia	4(33.33)	1(20.0)
Sepsis	0	0
Cardiac Arrest	4(33.3)	0
Blood Product Transfusion	15(68.18)	3(42.86)
Re-intubation	5(22.73)	1(14.29)
30-day Readmission	2(9.09)	0

Categorical data presented as number(%) unless otherwise indicated. Continuous data presented as Median(Interquartile Range). ESRD, end-stage renal disease; ESLD, end-stage liver disease; HCV, hepatitis C virus; MELD, model for end-stage liver disease; UA, unstable angina; STEMI, ST-elevation myocardial infarction; CAD, coronary artery disease

Table 4. Patient characteristics and postoperative outcomes of dialysis-dependent patients in Non-transplant and Pre-transplant groups

Characteristic/Outcome	Non-Transplant ESRD n=61	Pre-Transplant ESRD n=22	p-value
Age, years	63(11)	63.5(6)	0.7255
Gender			0.310
Male	40(65.57)	17(77.27)	
Female	21(34.43)	5(22.73)	
Body Mass Index	27.97(7.42)	30.29(4.07)	0.3169
Chronic Lung Disease	24(39.34)	6(27.27)	0.312
Cerebrovascular Disease	11(18.03)	8(36.36)	0.079
Hypertension	58(95.08)	21(95.45)	>0.999
Diabetes	46(75.41)	19(86.36)	0.374
Last Creatinine, mg/dL	5(3.6)	5.85(3.6)	0.3611
Ejection Fraction, %	50(25)	50(24)	0.9733
Dialysis			
Peritoneal	N/A	10(47.62)	
Hemo	N/A	11(52.38)	
Duration, months	N/A	34.71(31.58)	
Presentation			<0.0001
UA/Non-STEMI	40(65.57)	4(18.18)	
STEMI	3(4.92)	0	
Stable Angina	8(13.11)	3(13.64)	
Asymptomatic	10(16.39)	15(45.45)	
Postoperative Outcomes			
30-day Mortality	3(4.92)	2(9.09)	0.711
Length of Stay, days	7.29(9)	11.75(8)	0.3924
Total Ventilation, hours	5.87(12.13)	5(18.3)	0.6082
Surgical Site Infection	2(3.28)	1(4.55)	>0.999
In-Hospital Postoperative Events	29(47.54)	12(54.55)	0.573
Neurologic	3(4.92)	4(18.18)	0.076

Pneumonia	5(8.20)	4(18.18)	0.236
Sepsis	0	0	
Cardiac Arrest	4(6.56)	4(18.18)	0.073
Blood Product Transfusion	37(60.66)	15(68.18)	0.532
Reintubation	8(13.11)	5(22.73)	0.288
30-day Readmission	11(18.03)	4(18.18)	>0.999

Categorical data presented as number(%) unless otherwise indicated. Continuous data presented as Median(Interquartile Range). ESRD, end-stage renal disease; UA, unstable angina; STEMI, ST-elevation myocardial infarction

Figure 1. 30-day survival after CABG by study group

